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EXAMINER

SHAY, DAVID M

ART UNIT	PAPER NUMBER
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3735

DATE MAILED: 09/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/751,472

Applicant(s)

MODY ET AL.

Examiner

david shay

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on September 8, 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4-22,25-33,40-54,58-91,96,97,100-107,225,229-255,282 and 284-300 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 1,4-22,25-33,40-54,58-91,96,97,100-107,225,229-255,282 and 284-300.

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With respect to the rejections based on Lennox et al ('807) in combination with Costello et al and Cox et al (WO '187), applicant argues that the combination would lead person having ordinary skill in the art to perform a MAZE procedure on the prostate. The examiner must respectfully disagree. It is respectfully noted that Lennox et al ('807) teach cardiac procedures, and the use of the method of Costello et al in the method of Lennox et al ('807) is not based on any prostate specific motivation, thus this argument is not convincing.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 5, 9, 10-45, 106, 298, and 299 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Sinofsky et al.

See Figures 1-7 and columns 8, line 6 to column 17, line 15.

Claims 107, 225, 229-255, 282, 284-297, and 300 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lennox et al ('807) in combination with Costello et al and Cox et al (WO '187). Lennox et al, ('807) teach the use of flexible sheath with a window that can either be an open or covered window for transmitting radiation to tissue. Costello et al teach the equivalence of stationary and translatable energy applications. Cox et al (WO '187) teach the

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equivalence of laser, ultrasound, microwave, and cryosurgical energies as means of ablation, ablating tissue of the heart through a hole in the chest wall, use of a malleable end which can be pre-shaped; use of a sheath with a cut out window; and various manipulations of the device including ablating around the pulmonary vein, ablating on the epicardium, and positioning the device in three or more positions. It would have been obvious to the artisan of ordinary skill to employ the probe translations and optics of Costello et al in the method of Lennox et al ('807) since these are equivalent to the stationary probe and can create a longer lesion or to employ the covered window and flexible sheath of Lennox et al (807) in the method of Costello et al, since this will keep the optic clean, and to employ the maze procedure and ablation means of Cox et al (WO '187) in the combined method of Lennox et al ('807) and Costello et al, or to employ the particular ablation steps of the combined teachings of Lennox et al ('807) and Costello et al in the method of Cox et al (WO '187), since Cox et al (WO '187) teach no particular form for the non cryogenic ablation elements; to employ the various non cryogenic directional ablation element features claimed since these are merely a matter of choice and provides no unexpected result and are known means for providing the desirable functions of Cox et al (WO '187), such as directionality with these equivalent forms of ablation energy discussed by Cox et al (WO '187); to include a cutting member on the distal end of the sheath, since this would allow the cut to be made without introducing an additional tool, thus simplifying the procedure, as simplification is desirable, official notice of which is hereby taken; as well as to position the device adjacent to or in contact with the oblique or transverse sinuses as these are both structures associated with pulmonary veins and would be contacted in conjunction with the procedure shown in figure 21 of Cox et al (WO '187); to employ a key to enable the surgeon to

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recognize the orientation of the surgical device, since this is a notorious orientation indicator in the art; to sense the temperature, since this is notorious in ablation systems; to sense contact between the device and the tissue to be ablated, since this is notorious for ablating in sensitive organs such as the heart; to apply energy to assure that the ablation has been effective since this is also notorious in the art; official notice of all of these having already been taken and to perform a portion of a bypass graft procedure before or after forming one lesion, since bypass procedures are sometimes performed in conjunction with ablation procedures official notice of which is hereby taken, thus producing a method such as claimed.

Claims 1, 9, 43-45, 96, 97, 298, and 299 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lennox et al ('807) in combination with Costello et al and Diederich et al. Lennox et al ('807) teach the use of flexible sheath with a window that can either be an open or covered window for transmitting radiation to tissue. Costello et al teach the equivalence of stationary and translatable energy applications. Diederich et al teach the desirability of providing transmural ablations in the heart. It would have been obvious to the artisan of ordinary skill to employ the probe translations and optics of Costello et al in the method of Lennox et al ('807) since these are equivalent to the stationary probe and can create a longer lesion or to employ the covered window and flexible sheath of Lennox et al ('807) in the method of Costello et al, since this will keep the optic clean, and in either case, to employ the transmural lesions of Diederich et al in the method of Lennox et al ('807), since this is what provides conduction blockage, as taught by Diederich et al, thus producing a method such as claimed.

Claims 5-8, 10-22, 25-33, 40-42, 46-54, 58-72, 100-107, 225, 229-255, 282, 284-297, and 300 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lennox et al ('807) in

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combination with Costello et al and Diederich et al as applied to claims 1, 9, 43-45, 298 and 299 above, and further in combination with Cox et al (WO '187). Cox et al (WO '187) teach the equivalence of laser, ultrasound, microwave, and cryosurgical energies as means of ablation, ablating tissue of the heart through a hole in the chest wall, use of a malleable end which can be pre-shaped; use of a sheath with a cut out window; and various manipulations of the device including ablating around the pulmonary vein, ablating on the epicardium, and positioning the device in three or more positions. It would have been obvious to the artisan of ordinary skill to employ the maze procedure and ablation means of Cox et al (WO '187) in the combined method of Lennox et al ('807), Costello et al, and Diederich et al, or to employ the particular ablation steps of the combined teachings of Lennox et al ('807), Costello et al, and Diederich et al in the method of Cox et al (WO '187) since Cox et al (WO '187) teach no particular form for the non-cryogenic ablation elements; to employ the various non cryogenic directional ablation element features claimed since these are merely a matter of choice and provides no unexpected result and are known means for providing the desirable functions of Cox et al (WO '187), such as directionality with these equivalent forms of ablation energy discussed by Cox et al (WO '187); to include a cutting member on the distal end of the sheath, since this would allow the cut to be made without introducing an additional tool, thus simplifying the procedure, as simplification is desirable, official notice of which is hereby taken; as well as to position the device adjacent to or in contact with the oblique or transverse sinuses as these are both structures associated with pulmonary veins and would be contacted in conjunction with the procedure shown in figure 21 of Cox et al (WO '187); to employ a key to enable the surgeon to recognize the orientation of the surgical device, since this is a notorious orientation indicator in the art; to sense the temperature,

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since this is notorious in ablation systems; to sense contact between the device and the tissue to be ablated, since this is notorious for ablating in sensitive organs such as the heart; to apply energy to assure that the ablation has been effective since this is also notorious in the art; official notice of all of these having already been taken and to perform a portion of a bypass graft procedure before or after forming one lesion, since bypass procedures are sometimes performed in conjunction with ablation procedures official notice of which is hereby taken thus producing a method such as claimed.

Claims 70-79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lennox et al ('807) in combination with Costello et al and Diederich et al as applied to claims 1, 9, 43-45, 96, 97, 298 and 299 above, and further in combination with Swanson et al. Swanson et al teach using temperatures sensors to control ablation and electrodes to pace, map, etc. the heart in a maze procedure wherein the pulmonary vein is encircled. It would have been obvious to the artisan of ordinary skill to employ the sensors and the pulmonary vein encircling device in the combined method of Lennox et al ('807), Costello et al, and Diederich et al, since this would enable the performance of beneficial cardiac procedures such as maze or to employ the longitudinally translatable ablation element of the combined method of Lennox et al ('807), Costello et al, and Diederich et al in the method of Swanson et al, since this can create longer lesions with a single ablation element, this producing a method such as claimed.

Claims 80-91 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lennox et al ('807) in combination with Costello et al and Diederich et al as applied to claims 1, 9, 43-45, 96, 97, 298, and 299 above, and further in view of Kesten et al. Kesten et al teach delivering ablation devices with a pre-shaped sleeve to reach the ventricles via peripheral veins. It would

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have been obvious to the artisan of ordinary skills to employ the sheath, delivering route, and treatment region of Kesten et al in the combined method Lennox et al ('807), Costello et al, and Diederich et al or to employ the directional slidable probe in a sheath of the combined method of Lennox et al ('807), Costello et al, and Diederich et al in the method of Kesten et al, since this would allow the treatment of an elongated area without repositioning the device and in either case to treat one of the atria since these chambers are the site of beneficial treatments, official notice of which has already been taken and to employ an alternate access route such as the jugular or subclavian vein, since these are recognized catheter insertion routes in the art, official notice of which has already been taken, thus producing a method such as claimed.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 4-22, 25-33, 40-54, 58-91, 96, 97, 100-107, 225, 229-255, 282, and 284-300 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 7,033,352. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the patent anticipate the claims of the application. Accordingly, instant application claims are not

patentably distinct from the patent claims. Here, the patent claims require elements A, B, C, and D while instant application claim 1 only requires elements A, B, and C. Thus it is apparent that the more specific patent claims encompass the instant application claims. Following the rationale in *In re Goodman* cited in the preceding paragraph, where applicant has once been granted a patent containing a claim for the specific or narrower invention, applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer.

Claims 1, 4-22, 25-33, 40-54, 58-91, 96, 97, 100-107, 225, 229-255, 282, and 284-300 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,962,586. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the patent anticipate the claims of the application. Accordingly, instant application claims are not patentably distinct from the patent claims. Here, the patent claims require elements A, B, C, and D while instant application claim 1 only requires elements A, B, and C. Thus it is apparent that the more specific patent claims encompass the instant application claims. Following the rationale in *In re Goodman* cited in the preceding paragraph, where applicant has once been granted a patent containing a claim for the specific or narrower invention, applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer.

Claims 1, 4-22, 25-33, 40-54, 58-91, 96, 97, 100-107, 225, 229-255, 282, and 284-300 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 6-13, 19-64, and 68 of U.S. Patent No. 6,673,068. Although the

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conflicting claims are not identical, they are not patentably distinct from each other because the claims of the patent anticipate the claims of the application. Accordingly, instant application claims are not patentably distinct from the patent claims. Here, the patent claims require elements A, B, C, and D while instant application claim 1 only requires elements A, B, and C. Thus it is apparent that the more specific patent claims encompass the instant application claims. Following the rationale in *In re Goodman* cited in the preceding paragraph, where applicant has once been granted a patent containing a claim for the specific or narrower invention, applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer.

Claims 1, 4-22, 25-33, 40-54, 58-91, 96, 97, 100-107, 225, 229-255, 282, and 284-300 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-29 of U.S. Patent No. 6,312,427. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the patent anticipate the claims of the application. Accordingly, instant application claims are not patentably distinct from the patent claims. Here, the patent claims require elements A, B, C, and D while instant application claim 1 only requires elements A, B, and C. Thus it is apparent that the more specific patent claims encompass the instant application claims. Following the rationale in *In re Goodman* cited in the preceding paragraph, where applicant has once been granted a patent containing a claim for the specific or narrower invention, applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer.

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Claims 1, 4-22, 25-33, 40-54, 58-91, 96, 97, 100-107, 225, 229-255, 282, and 284-300 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 12, 13, 15, 16, 18, and 19 of U.S. Patent No. 6,245,062. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the patent anticipate the claims of the application. Accordingly, instant application claims are not patentably distinct from the patent claims. Here, the patent claims require elements A, B, C, and D while instant application claim 1 only requires elements A, B, and C. Thus it is apparent that the more specific patent claims encompass the instant application claims. Following the rationale in *In re Goodman* cited in the preceding paragraph, where applicant has once been granted a patent containing a claim for the specific or narrower invention, applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer.

Claims 1, 4-22, 25-33, 40-54, 58-91, 96, 97, 100-107, 225, 229-255, 282, and 284-300 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 5, 22, 43, 47-49, 53, 54, 97, and 116 of U.S. Patent Application No. 10/211,685. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application anticipate the claims of the instant application, as the use of the device would read on the method. Accordingly, instant application claims are not patentably distinct from the copending application claims. Here, the copending application claims require elements A, B, C, and D while instant application claims only requires elements A, B, and C. Thus it is apparent that the more specific copending application claims encompass the instant application claims. Following

the rationale in *In re Goodman* cited in the preceding paragraph, where applicant has once been granted a patent containing a claim for the specific or narrower invention, applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, 4-22, 25-33, 40-54, 58-91, 96, 97, 100-107, 225, 229-255, 282, and 284-300 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 8, and 14-17 of U.S. Patent Application No. 10/253,737. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application anticipate the claims of the instant application, as the use of the device would read on the method. Accordingly, instant application claims are not patentably distinct from the copending application claims. Here, the copending application claims require elements A, B, C, and D while instant application claims only requires elements A, B, and C. Thus it is apparent that the more specific copending application claims encompass the instant application claims. Following the rationale in *In re Goodman* cited in the preceding paragraph, where applicant has once been granted a patent containing a claim for the specific or narrower invention, applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, 4-22, 25-33, 40-54, 58-91, 96, 97, 100-107, 225, 229-255, 282, and 284-300 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 15-42 of U.S. Patent Application No. 10/348,256. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application anticipate the claims of the instant application, as the use of the device would read on the method. Accordingly, instant application claims are not patentably distinct from the copending application claims. Here, the copending application claims require elements A, B, C, and D while instant application claims only requires elements A, B, and C. Thus it is apparent that the more specific copending application claims encompass the instant application claims. Following the rationale in *In re Goodman* cited in the preceding paragraph, where applicant has once been granted a patent containing a claim for the specific or narrower invention, applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, 4-22, 25-33, 40-54, 58-91, 96, 97, 100-107, 225, 229-255, 282, and 284-300 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-72 of U.S. Patent Application No. 10/897,232. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application anticipate the claims of the instant application, as the use of the device would read on the method. Accordingly, instant application claims are

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not patentably distinct from the copending application claims. Here, the copending application claims require elements A, B, C, and D while instant application claims only requires elements A, B, and C. Thus it is apparent that the more specific copending application claims encompass the instant application claims. Following the rationale in *In re Goodman* cited in the preceding paragraph, where applicant has once been granted a patent containing a claim for the specific or narrower invention, applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's arguments filed July 17, 2006 have been fully considered but they are not persuasive. The arguments are not persuasive for the reasons set forth above.

Applicant's arguments with respect to claims 1, 5, 9, 10-45, 106, 298, and 299 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to david shay whose telephone number is (571) 272-4773. The examiner can normally be reached on Tuesday through Friday from 6:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II, can be reached on Monday, Tuesday, Wednesday, Thursday, and Friday. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications

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may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



DAVID M. SHAY
PRIMARY EXAMINER
GROUP 330